UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

CONNIE POULIN, Individually, and as Personal Representative of the Estate of David Poulin, Deceased,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

DECISION and ORDER

22-CV-553JLS(F)

APPEARANCES:

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In this strict products liability case, Plaintiff alleges Defendant failed to warn

Plaintiff's husband, David Poulin ("Decedent"), of potential dangers arising in connection with a Greenfield Interior Vena Cava Filter ("the IVC Filter" or "Greenfield Filter") that was manufactured by Defendant. Defendant's IVC Filter is a medical device implanted in a blood vessel, typically a deep leg vein, to prevent blood clots from traveling into a patient's heart and lungs and to maintain blood flow to the heart and lungs. On May 18, 1999, Decedent underwent surgery for an implant of the IVC Filter in Decedent's right inferior vena cava. On June 15, 2020, Decedent suffered a major heart attack and died. According to an autopsy, Decedent's death resulted from blood clots in Decedent's lungs partially caused by the IVC Filter becoming perforated and occluded with a blood clot. As a result, Plaintiff commenced this action against Defendant asserting the Defendant's IVC Filter was defective and caused Decedent's death. Specifically, Plaintiff alleged several claims for product liability, including a failure to warn of risks of migration of the IVC Filter from the implantation site, perforation of a blood vessel (Decedent's right inferior vena cava) wall, causing blood clots, perforation and imbedding in the wall of Decedent's right vena cava. In a Report and Recommendation filed December 9, 2022 (Dkt. 22), the undersigned recommended that Plaintiff's claims for defective design, breach of warranty, consumer fraud and deceptive trade practice be dismissed. In a Decision and Order, filed January 9, 2023 (Dkt. 23), District Judge John L. Sinatra, Jr. accepted the Report and Recommendation and referred the matter back to the undersigned for further proceedings on Plaintiff's remaining failure to warn claim.

Plaintiff commenced discovery on June 26, 2023, by serving Plaintiff's First Set of Interrogatories and Requests for Production of Documents ("Plaintiff's Discovery

Requests"). Defendants' responses to Plaintiff's Discovery Requests were served on August 25, 2023. Despite counsels' several unsuccessful attempts to resolve Defendant's objections to Plaintiff's requests over the next six months, Plaintiff served the instant motion on February 21, 2024 (Dkt. 30) ("Plaintiff's Motion"). Defendant's Response to Plaintiff's Motion To Compel and Defendant's Motion for a Protective Order, was filed March 14, 2024 (Dkt. 37) ("Defendant's Response"), which included objections based on lack of relevancy, proportionality, overbreadth, and undue burdensomeness. *See, e.g.*, (Dkt. 30-4) at 8. In particular, Defendant asserted Plaintiff had failed to identify the specific Defendant's IVC Filter that had been implanted in Decedent in 1999 and that Plaintiff's requests for information concerning Defendant's IVC devices manufactured after Decedent's death in 2020 render Plaintiff's requests overly broad by seeking irrelevant information. Defendant's Response (Dkt. 37) at 5-7. Plaintiff's Reply Memorandum of Law in Further Support of Plaintiff's Motion To Compel And In Opposition to Defendant's Motion For A Protective Order was filed March 26, 2024 (Dkt. 40) ("Plaintiff's Reply").

On April 4, 2024, Plaintiff filed Plaintiff's Notice of Newly Discovered Evidence As It Relates To Plaintiff's Motion To Compel (Dkt. 41) ("Plaintiff's Notice of Newly Discovered Evidence"), in which Plaintiff asserted Plaintiff had received from the Cleveland Clinic information confirming that the specific type of Defendant's IVC Filter implanted in Decedent in 1999 was a Stainless-Steel Greenfield Vena Cava Filter surgically implanted in Decedent at the WCA Hospital in Jamestown, New York. *See* Dkt. 41 at 1. As a result of this information describing Defendant's product, Plaintiff requested that Defendant's objections to Plaintiff's Discovery Requests based on an

asserted lack of product identification by Plaintiff be stricken ("Plaintiff's Motion to Strike"). *Id.* By Text Order, filed October 2, 2024, the court directed Defendant to file a response to Plaintiff's Notice of Newly Discovered Evidence and Motion to Strike. (Dkt. 42). On October 11, 2024, Defendant filed its Response to Plaintiff's Notice of Newly Discovered Evidence and Motion To Strike (Dkt. 46) ("Defendant's Response to Plaintiff's Notice of Newly Discovered Evidence and Motion to Strike").

In Defendant's Response To Plaintiff's Notice of Newly Discovered Evidence and Motion to Strike, Defendant agreed to withdraw its objection to Plaintiff's Discovery Requests based on a lack of product identification; however, Defendant reasserted its other objections contending Plaintiff's requests pertaining to product history over 25 years are overly broad, "not relevant to the facts at hand" and disproportionately burdensome. Dkt. 46 at 1. Additionally, in Defendant's Response to Plaintiff's Notice of Newly Discovered Evidence and Motion to Strike, Defendant agreed to produce all documents pertaining to Defendant's Stainless-Steel Greenfield IVC File for the relevant time period as defined by Plaintiff, *i.e.*, 1995 to 2002, *see* (Dkt. 30-2) ¶ 21, relating to the same injuries as Plaintiff alleges, specifically, "perforation, occlusion, and recurrent pulmonary embolism." Dkt. 46 at 1-2.[1] Defendant also agreed to produce all Defendant's communications with the implanting physician, one Dr. Gritters, and the hospital at which Decedent received the implant, WCA Hospital in Jamestown, New York, regarding the Defendant's IVC Filter and the Decedent. *Id.* Beyond these parameters, Defendant declined to comply with Plaintiff's Discovery Requests. *Id.* In Plaintiff's Reply to Defendant's Response to Plaintiff's Motion to Strike, filed October 15,

[1] Defendant's enumeration fails to include that Plaintiff also alleges a "risk of migration." *See* Amended Complaint (Dkt. 1-1) ¶¶ 23, 24, 54, 87, 90 and 92.

2024 (Dkt. 47), Plaintiff states Plaintiff relies on Plaintiff's prior briefing in support of Plaintiff's motion and that Plaintiff's Discovery Requests remaining at issue be granted. Dkt. 47 at 1. According to Plaintiff, the following discovery requests remain at issue on Plaintiff's motion: Interrogatories Nos. 6 and 7 and Requests for Production of Documents Nos. 5, 6, 7, 10, 11 and 15. Plaintiff's Reply (Dkt. 40) at 5-6.

Interrogatory No. 6.

Interrogatory No. 6 asks Defendant to identify "all IVC Filters manufactured by . . . [Defendant] that were subject to a recall or adverse event report from 1995 to the present." Plaintiff's Exh. 1 (Dkt. 30-2) at 5. Defendant's response to Interrogatory No. 6 asserts the interrogatory is overbroad, fails to seek relevant information, requests information disproportionate to the needs of the case, and is not reasonably calculated to lead to the discovery of admissible evidence. Dkt. 37 at 8. In support of Defendant's objections, Defendant contends that the interrogatory requests information extending over a 30-year period and includes devices manufactured by Defendant after Decedent's implantation and death, and that information "learned [by Defendant] after the date of implant would not have a bearing on Plaintiff's failure to warn claim." *Id.* Defendant also argues the interrogatory is not limited to the same or similar incidents (*i.e.*, perforation and occlusion of the IVC filter) and is therefore irrelevant to Plaintiff's claim, that the burden to Defendant to glean Defendant's records of dissimilar incidents to enable Defendant to answer the interrogatory outweighs any potential benefit to Plaintiff, and, that recall information concerning medical devices like Defendant's Greenfield IVC Filter is publicly available on the U.S. Food and Drug Adminstration's ("the FDA") website. *See* (Dkt. 37) at 8-9. In Plaintiff's Reply, Plaintiff requests

Defendant identify all pertinent adverse incident reports from 1999 to "the date of [Decedent's] death," or June 2020, rather than "to present," *i.e.,* 2024, as Plaintiff's Interrogatory No. 6 requested. *See* Dkt. 40 at 4.

Plaintiff responds by arguing that adverse events and recall reports are relevant to Plaintiff's failure to warn claim given that such reports "constitute evidence of the risks to patients [like Decedent] with Greenfield IVC Filters which Defendant had a duty to warn against." Plaintiff's Reply (Dkt. 40) at 4 (citing *Kaemmlein v. Abbott Laboratories*, 564 F.Supp.3d 58, 73 (E.D.N.Y. 2021) (stating that, under New York law, a medical device manufacturer has a "continuous" duty to warn the medical community of all "potential dangers" of which it knows or should have known and must take steps "as are reasonably necessary to bring that knowledge to the attention of the medical [community].") (citing caselaw) (internal quotation marks omitted). Under New York law, a manufacturer's duty to warn encompasses a failure to warn based on incidents occurring after "manufacture or sale . . . involving dangers in the product of which warning should be given to users." *Cover v. Cohn*, 461 N.E.2d 864, 871 (N.Y. 1984) ("*Cover*") (citing caselaw and authorities). In *Cover*, the court further stated that the notice to a manufacturer of problems revealed by the use of the product sufficient to "trigger [the manufacturer's] post-delivery duty to warn . . . [is] a function of the degree of danger which the problem involves and the number of instances reported." *Id.* Defendant's relevancy objection to Interrogatory No. 6 also overlooks that as one who had received a Greenfield IVC Filter, Decedent could have benefitted from knowledge of adverse events occurring after his implant such as perforation, occlusion, recurrent pulmonary embolism and migration involving the IVC Filter, including consideration of

potential retrieval of the device and implanting a different device. Thus, it is incorrect to assert, as Defendant does, that information of adverse incidents and recalls occurring after the date of Plaintiff's implant has no bearing on Plaintiff's failure to warn claim and thus seeks irrelevant information. Moreover, that Plaintiff's Interrogatory No. 6 seeks all adverse events information concerning the Greenfield IVC Filter does not avoid discovery based on an asserted lack of relevancy as Plaintiff is entitled to all such responsive information in order to determine whether Defendant's answer includes specific data supportive of Plaintiff's failure to warn claim. *See Sokolovic v. CVS Health*, 2023 WL 2742148, at ** 14-15 (E.D.N.Y. Mar. 31, 2023) (denying summary judgment where safety data sheets describing hazards associated with allegedly dangerous product that was the subject of strict liability action based on failure to warn were relevant to whether the alleged injury was reasonably foreseeable requiring a manufacturer's warning); *Culligan v. Yamaha Motor Corporation, USA*, 110 F.R.D. 122, 125 (S.D.N.Y. 1986) (holding with regard to products liability personal injury action based on failure to warn claim arising out of accident in which an all-terrain vehicle flipped while the plaintiff was operating the vehicle, that postmanufacturing testing data for the vehicle was relevant to the vehicle's stability as well as to whether the defendant manufacturer and distributor was required to disclose the information). Further, whether an adverse incident falls within the categories of potential risks alleged by Plaintiff is apt to involve specialized medical knowledge for evaluation. Defendant's objection on the ground that Interrogatory No. 6 seeks irrelevant information is therefore OVERRULED.

As regards to Defendant's assertion that compliance with Interrogatory No. 6 would entail excessive efforts by Defendant, amounting to undue burdensomeness,

Defendant fails to provide an affidavit by a person with knowledge of Defendant's filing system, including Defendant's use of computerized records maintained by Defendant attesting to the fact of alleged excessive burden to Defendant in order to access information needed to respond to Interrogatory No. 6. *See Cliffstar Corp. v. Sunsweet Growers, Inc.*, 218 F.R.D. 65, 70 (W.D.N.Y. 2003) ("[F]or a burdensomeness objection to be sustained, a motion to compel on this ground must be opposed by an affidavit of a person with knowledge of the record keeping system with the requested party explaining in reasonable detail the factual basis for such an objection." (citing cases)). As such, Defendants' objection on this ground is OVERRULED. Defendant's assertion that Plaintiff's Interrogatory No. 6 requests information disproportionate to the case is likewise without merit.

Under Fed.R.Civ.P. 26(b)(1) ("Rule 26(b)(1)"), information sought by a party must be proportional to the needs of the case and is determined by the court's weighing of six factors: (1) the importance of the issues at stake in the case, (2) the amount in controversy, (3) the parties' access to relevant information, (4) the parties' resources, (5) the importance of the requested discovery in resolving the issues in the case, and (6) whether the burden or expense of the requested discovery outweighs its likely benefit. The court has broad discretion in weighing these Rule 26(b)(1) factors, *see ValveTech, Inc. v. Aerojet Rocketdyne, Inc.*, 2021 WL 630910, at * 2 (W.D.N.Y. Feb. 18, 2021), no single factor is determinative and the burden to show a lack of proportionality is on the party seeking to avoid the discovery at issue. *See Wall v. Reliance Standard Life Insurance Company*, 341 F.R.D. 1, 5 (D.D.C. 2022) (no single factor is determinative), and *Mortgage Resolution Servicing, LLC v. JPMorgan Chase Bank,*

N.A., 2016 WL 3906712, at *3 *S.D.N.Y. July 14, 2016) (the party resisting discovery has the burden of showing a lack of relevancy or proportionality).

As regards the first factor, the importance of the issues at stake is self-explanatory as the case involves damages for death of a patient who utilized the Defendant's IVC Filter. Second, the amount in controversy is unknown as the Amended Complaint does not include a specific request for a monetary amount of compensatory and punitive damages but a substantial award is reasonably foreseeable should Plaintiff prevail at trial. *See In re Joint Eastern and Southern District Asbestos Litigation*, 726 F.Supp. 426, 432-33 (E.D.N.Y. 1989) (damages in strict products liability action based on failure to warn would include future income plaintiff would have earned over number of years he would have lived if not for death caused by the manufacturer's failure to warn). *See* Dkt. 1-1 at 57. Third, the record indicates that while Defendant has access to the underlying records, Defendant also asserts that similar information is available to Plaintiff at the FDA public website, *see* Defendant's Response (Dkt. 37) at 9. However, courts have serious doubts regarding the probative value of the FDA's MAUDE website.[2] *See Keen v. C.R. Bard, Inc.*, 480 F.Supp.3d 624, 632-33 (E.D.Pa. 2020) (court declined to accept data from FDA MAUDE database website based on the website's disclaimer about "potential submission of incomplete, inaccurate, untimely data," thereby impairing its efficacy in determining "the incidence or prevalence of an event"); *see also Coolidge v. United States*, 2020 WL 3467423, at *28 (W.D.N.Y. June 25, 2020) (in a case alleging defendant liable for decedent's death based on misplaced

[2] MAUDE, an acronym for the Manufacturer and User Facility Device Experience database, is a shareable public database containing information regarding adverse events involving the use of medical devices approved by the FDA for public use. *See Bull v. St. Jude Medical, Inc.*, 2018 WL 3397544, at *2 (E.D.Pa. July 12, 2018).

artery stent graft court declined to rely on MAUDE website information to determine standard of care where court found website's data failed to indicate "evidence or prevalence" of stent migration and that the website is "not reviewed by clinicians," nor is it considered as "scientific," or being "peer-reviewed"); *Tomaselli v. Zimmer, Inc.*, 2015 WL 13888410, at *2 (S.D.N.Y. Mar. 23, 2015) (rejecting use of MAUDE reports "because the reports could be 'incomplete, inaccurate, untimely, unverified, or biased'"). Further, Defendant fails to provide any basis, such as an affidavit by a knowledgeable person, attesting to the accuracy and completeness of the information concerning the Defendant's Greenfield IVC filters adverse incident reports submitted by Defendant to the MAUDE website. Under Fed.R.Civ.P. 26(b)(1), Plaintiff is entitled to accurate and complete discovery responses. *See Meadowbrook-Richman, Inc. v. Associated Financial Corp.*, 253 F.Supp.2d 666, 680 (S.D.N.Y. 2003) (observing the plaintiff's failure to provide complete and accurate responses to the defendant's discovery requests was an appropriate basis for awarding sanctions). Fourth, the parties' relative resources factor supports Plaintiff and Defendant does not dispute Defendant has superior resources. Fifth, the importance of the issue, whether the Defendant had notice of potential risks involving Defendant's Greenfield IVC Filter as implanted in Decedent that should have prompted a warning of such risks to Decedent and his physicians is critical to Plaintiff's burden of proof. *See State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 Fed.Appx. 8, 10 (2d Cir. 2011) (citing *Liriano v. Hobart Corp.*, 700 N.E.2d 303, 305 (N.Y. 1998)); *Cover*, 461 N.E.2d at 71. Sixth, whether the burden or expense of the requested discovery, *viz.*, Defendant's compliance with Plaintiff's Interrogatory No. 6 outweighs its likely benefit, weighs in Plaintiff's favor as Defendant's

probable use of computerized record-keeping would support that the burden on Defendant to access Defendant's records to enable Defendant to answer Interrogatory No. 6 is minimal compared to the importance of the requested information to Plaintiff's ability to meet its burden of proof at trial. *See Ferira v. State Farm Fire & Casualty Co.*, 2018 WL 3032554, at * 2 (D.S.C. June 18, 2018) ("[T]he burden to Defendant—a large corporation presumably with personnel dedicated to maintaining electronic records of clients' policies—of producing the policies does not outweigh a likelihood that Plaintiff may benefit from reviewing them."); *Annex Books, Inc. v. City of Indianapolis*, 2011 WL 3298425, at *2 (S.D. Ind. Aug. 1, 2011) ("[T]he burden of producing Plaintiffs' electronic bookkeeping records does not outweigh the likely benefit of production."), *aff'd*, 2012 WL 892170 (S.D. Ind. Mar. 14, 2012). Accordingly, Defendant has failed to carry its burden to establish a lack of proportionality with respect to Defendant's required compliance with Interrogatory No. 6. *See Mortgage Resolution Servicing, LLC,* 2016 WL 3906712, at *3 (the party resisting discovery has burden of showing a lack of relevancy or proportionality). As such, Defendant's objection to Interrogatory No. 6 on this ground is OVERRULED.

Finally, Defendant contends that to the extent Interrogatory No. 6 requests Defendant identify "all" IVC Filters manufactured by Defendant that "were subject to a recall or adverse event report from 1995 to the present," *see* Dkt. 30-2 at 5 (underlining added), such request is overly broad as requesting information on products not at issue. *See* Defendant's Response (Dkt. 37) at 8. Plaintiff has not responded to Defendant's objection. *See* Plaintiff's Reply (Dkt. 40) at 4 (asserting Defendant's insistence that Plaintiff specifically identify the particular IVC product involved in Decedent's

implantation is meritless as Defendant's duty to warn is continuous). However, given Plaintiff has now particularized the alleged offending product as Defendant's Stainless-Steel Greenfield IVC Filter, *see* Plaintiff's Notice of Newly Discovered Evidence (Dkt. 41) at 1, it is apparent that Defendant's response to this interrogatory should be limited to Defendant's Greenfield IVC Filter, and any substantially similar IVC Filters, rather than all IVC Filters manufactured by Defendant during the period of 1995 to 2000 as Interrogatory No. 6, modified by Plaintiff's Reply, requests. *See Hasbrouck v. BankAmerica Housing Services,* 187 F.R.D. 453, 461-62 (N.D.N.Y. 1999) (limiting scope of discovery to that pertaining to similar claims and injuries). Additionally, Plaintiff's Reply indicates Plaintiff's modification of the scope of the interrogatory to be limited to Defendant's Greenfield IVC Filter, rather than "all" of Defendant's IVC Filters as the interrogatory demands. *See* Plaintiff's Reply (Dkt. 40) at 4. Accordingly, Defendant's objection to Interrogatory No. 6 on this ground is OVERRULED and Plaintiff's Motion is GRANTED as to this interrogatory.

Interrogatory No. 7.

In this interrogatory, Plaintiff requests Defendant to identify all Defendant's employees and others involved in the drafting of warnings or instructions for use ("IFU's") of the Greenfield IVC Filters from 1995 to the present. *See* (Dkt. 30-2) at 6. Plaintiff subsequently agreed to limit the scope of the interrogatory to any Defendant's IVC Filters Defendant sold to the WCA Hospital in Jamestown, New York, between 1995 and 1999. *See* (Dkt. 37) at 9; (Dkt. 40) at 4. Defendant objects to the interrogatory on the grounds of lack of relevance, overbreadth, and disproportionality. *See* (Dkt. 37) at 9. Plaintiff argues in opposition that circumstantial evidence satisfies

the need to provide precise product identification (Dkt. 40 at 4), an issue now moot in light of Plaintiff's Notice of Newly Discovered Evidence and Defendant's acquiescence in such Notice. *See* (Dkt. 46) at 1-2.

To prevail on a failure to warn claim, a plaintiff must prove that a manufacturer has a duty to warn against dangers resulting from foreseeable dangers about which it knew or should have known, and that failure to do so proximately caused plaintiff's harm. *See State Farm Fire & Cas. Co.,* 426 Fed.Appx. at 10 (citing *Liriano*, 700 N.E.2d at 305). A manufacturer's notice of the potential risk of danger is therefore prerequisite to a successful failure to warn claim. Accordingly, Defendant's relevancy objection to Interrogatory No. 7 is OVERRULED.

As to Defendant's objection asserting the interrogatory is overbroad, Plaintiff fails to explain why it is necessary to learn the identify of all persons involved in the drafting of the Greenfield IVC Filter warnings and instructions for use. It is more reasonable to expect that Defendant's employees and others who had direct and primary responsibility for drafting warnings or IFUs for the Greenfield IVC Filter are persons likely to have actual knowledge of any risks in the use of the IVC Filter of which Defendant had notice and caused Defendant to generate a warning or an IFU in connection with usage of the filter. It is therefore not essential to Plaintiff's ability to obtain evidence sufficient to meet Plaintiff's burden of proof at trial on Plaintiff's failure to warn claim to seek the identity of all persons involved in the production of the warnings or IFUs in regard to the Greenfield IVC Filter. The interrogatory should therefore be amended to limit its scope to Defendant's employees with direct and primary responsibility for such preparation. Finally, the court also finds Plaintiff's limitation of the

interrogatory to the five-year period, 1995 to 1999, to Greenfield IVC Filters sold by Defendant to WCA Hospital to be a substantial reduction in the burden to Defendant's efforts to respond. *See* (Dkt. 37) at 9; (Dkt. 40) at 4. Defendant's objection on this ground is therefore OVERRULED in part and SUSTAINED in part. Based on the foregoing, it is not necessary for the court to address Defendant's objection based on lack of proportionality.

Plaintiff's Document Requests.

Request for Production No. 5.

In this request, Plaintiff seeks every communication between Defendant and any physician or other employee of Brooks Memorial Hospital or the WCA Hospital in Chautauqua County relating to Defendant's Greenfield IVC Filter during the period 1995 to 2002. *See* (Dkt. 30-2) ¶ 21 (the Relevant Time Period for Plaintiff's Discovery Requests, unless otherwise noted, is 1995-2002). After initially objecting based on a lack of relevance, overbreadth, and proportionality, *see* Dkt. 37 at 10, Defendant has agreed to produce "all available" documents pertaining to the Stainless-Steel Greenfield IVC Filter relating to the same alleged injuries in the case, *i.e.*, perforation, occlusion, and recurrent pulmonary embolisms, Defendant had with Dr. Gritters, Decedent's implant physician and the WCA Hospital where Plaintiff received the implant, for the period 1995 to 2002. (Dkt. 46) at 1-2. Plaintiff insists on the broader scope of Request No. 5. *See* (Dkt. 47) at 1. Defendant's document retention policy, produced to Plaintiff, indicates that Defendant's sales and marketing correspondence are retained for two years, invoices and purchase orders are retained for seven years and "promotional material and complaints" are retained for 15 years. (Dkt. 37) at 11. Plaintiff does not

challenge Defendant's representation regarding Defendant's document retention policies.

As discussed, *see, supra*, at 6-7, information concerning a medical device manufacturer's product risks of danger is a continuous duty rendering post-injury information providing notice of such risks to the manufacturer relevant to a failure to warn claim. *See Kaemmlein,* 564 F.Supp.3d at 73; *Cover*, 461 N.E.2d at 871. Defendant's relevancy objection is therefore OVERRULED. However, as to Defendant's burdensomeness and disproportionality objections, the court finds that Defendant's objections have merit. In particular, while Plaintiff requests all documents relating to any injury to complications experienced by a patient implanted with a Greenfield IVC Filter, courts limit production to the same or substantially similar injury to that as suffered by a patient. *See Hasbrouck*, 187 F.R.D. at 461-62 (limiting scope of discovery to that pertaining to similar claims and injuries). Thus, to the extent Request No. 5 requests communications relating to other than such injuries, in this case, perforation, occlusion, migration, and recurrent pulmonary embolisms, the request is overly broad. However, as to document production required by Fed.R.Civ.P. 34(a), it is basic that non-existent documents cannot be produced. *See Lopez v. Chappius*, 2022 WL 2974033, at *1 (W.D.N.Y. July 27, 2022) ("Of course, [a] court cannot compel defendant to produce documents that do not exist." (quoting *Bonano v. Tillinghast*, 2021 WL 1117027, *4 (W.D.N.Y. 2021)). To the extent that Plaintiff's requests for documents no longer available for production as a result of Defendant's document retention policies, Plaintiff's request is therefore futile. *See Bonano*, 2021 WL 1117027 at *4. Accordingly, Plaintiff's motion regarding Request No. 5 is GRANTED in part, and

DENIED in part.[3]

Request for Production No. 6.

In this request, Plaintiff seeks every document reflecting any communications Defendant's sales representatives had with any patient or physician or hospital in Chautauqua County during the period 1995 to 2002. (Dkt. 30-2) at 7. Defendant's objections include lack of relevancy, disproportionality, and overbreadth. *See* (Dkt. 37) at 11. To the extent Defendant argues that post-implant communications are irrelevant and disproportionate, such objections are OVERRULED. *See, supra*, at 6-7, 8-11. However, insofar as the request seeks communications relating to injuries other than those allegedly suffered by Decedent, Defendant's objection based on a lack relevance and overbroadness are SUSTAINED. *Cf. Hasbrouck*, 187 F.R.D. at 461-62. Accordingly, Defendant shall produce all communications pertaining to the same or substantially similar injuries alleged to have been suffered by Plaintiff, between Defendant, Dr. Gritters, and the WCA Hospital regarding Defendant's Stainless-Steel Greenfield IVC Filter, during the period 1995 and 2002 to the extent such documents are available.

Request for Production No. 7.

In this request, Plaintiff seeks any and all recalls, complaints, and adverse event reports with respect to Defendant's Greenfield IVC Filters for the period 1995 - 2002. *See* (Dkt. 30-2) at 7. Defendant's objections include lack of relevancy, disproportionality, and overbreadth. *See* Dkt. 37 at 12. Defendant also asserts such information is available to Plaintiff on the FDA website. *See* (Dkt. 37) at 12-13. As

[3] Based on the foregoing, addressing Defendant's proportionality and privilege objections (*see* Dkt. 37 at 10) is unnecessary.

discussed, *supra*, at 6-7, the requested documents, specifically relating to recalls, and adverse incidents involving the IVC Filter Plaintiff requests are relevant to Plaintiff's failure to warn claim. Defendant's disproportionality and overbreadth objections are also without merit. *See, supra*, at 8-1, 11-12. Additionally, that such information may be available to Plaintiff on the FDA MAUDE website is not a bar to Plaintiff's request. *See, supra*, at 9-10. Therefore, Plaintiff's Motion with respect to Request No. 7 is GRANTED. Defendant shall produce all available documents responsive to Request No. 7 for the period of 1995 to 2002.

Request for Production No. 10.

In this request, Plaintiff seeks all documents Defendant submitted to the FDA in Defendant's effort to gain FDA approval of the Greenfield IVC Filter pursuant to Section 510(k) of the Medical Device Amendments of 1976 ("§ 510(k)"). *See* (Dkt. 30-2) at 7. Defendant's principal objection is that Defendant's § 510(k) submissions are not relevant to Plaintiff's failure to warn claims because of Plaintiff's lack of product identification. *See* (Dkt. 37) at 14. Defendant also objects asserting Defendant's compliance with the request would reveal proprietary information. *See id.* Defendant's relevancy objection is now moot in light of Plaintiff's Notice of Newly Discovered Evidence (Dkt. 41) and Defendant's acquiescence. *See* (Dkt. 46) at 1-2. As to Defendant's complaint that production responsive to Request No. 10 would impair Defendant's proprietary information, Plaintiff contends, correctly, that such concern can be obviated by execution of a confidentiality agreement between the parties. *See Davis v. AT&T Corp.*, 1998 WL 912012, at *1 (W.D.N.Y. Dec. 23, 1998) (opposing parties agreed a protective order was appropriate to protect the proprietary and confidential

nature of the information that was subject to discovery (citing Fed.R.Civ.P. 26(c)) providing the court may issue an order protecting, *inter alia*, a party from revealing trade secrets and other commercial information, in other than a designated manner related to the litigation)). Moreover, § 510(k)(2), 21 U.S.C. § 360(k), requires that a Class III medical device,[4] such as Defendant's Greenfield IVC Filter, be approved by the FDA based on the device being "substantially equivalent" to a device previously approved by the FDA. *Id.* (referencing 21 U.S.C. § 360e(b)(1)(B), a "predicate" device). *See also,* 21 C.F.R. § 807.92(a)(3) ("the predicate device"). A § 510(k) summary or statement submitted to the FDA to obtain approval of a device pursuant to § 510(k) may contain a "discussion of the safety or effectiveness data obtained from [clinical tests performed on the device] . . . with specific reference to adverse effects and complications," 21 C.F.R. § 807.92(b)(2) ("a § 510(k) summary"), or "all information . . . on safety and effectiveness" of the proposed device (21 C.F.R. § 807.93 ("a § 510(k) statement").

Defendant does not dispute that the Greenfield IVC Filter was approved by the FDA as a Class III device pursuant to § 510(k). Nor does Defendant dispute that Defendant's § 510(k) application for the Defendant's Greenfield IVC Filter was approved by the FDA as substantially equivalent to a predicate device. Further, Defendant also does not indicate whether its § 510(k) summary or statement included any information concerning the device's safety and effectiveness. Instead, Defendant asserts it cannot comply with Plaintiff's Request No. 10 as to do so would disclose proprietary information. *See* (Dkt. 37) at 14. However, by regulation, the FDA is required to make

[4] A Class III medical device is one that cannot be classified as either a Class I or Class II device because of a lack of sufficient information regarding controls or a lack of a performance standard to provide reasonable assurance of the device's safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(C).

available to the public a § 510(k) summary of the applicant's safety and effectiveness data within 30 days of its approval of the § 510(k) application for the device. *See* 21 C.F.R. § 807.95(d). Further, 21 C.F.R. § 807.93(a)(1), requires that a submitting party agrees to provide similar information in response to a request if the device has been approved by the FDA as substantially equivalent to a predicate device based on a § 510(k) statement. Significantly, Defendant fails to provide an averment that production in response to Request No. 10 would entail proprietary disclosures outside the scope of information Defendant was required to provide to the FDA in either a § 510(k) summary or statement. Thus, Defendant's objections based on lack of relevancy and disclosure of proprietary information are without merit. Accordingly, Plaintiff's motion with respect to Request No. 10 is GRANTED. As Plaintiff also was agreeable to limiting Plaintiff's request to those Greenfield IVC Filters Defendant sold to Brooks Memorial Hospital for the year 1999, *see* (Dkt. 40) at 6, presumably Plaintiff remains agreeable to a similar limitation to Greenfield IVC Filters Defendant sold to WCA Hospital where Plaintiff received the IVC Filter implant in 1999.

Request for Production No. 11.

In this request, Plaintiff seeks production of all documents relating to whether Defendant's effort to obtain FDA approval of the Greenfield IVC Filter pursuant to § 510(k) of the Medical Device Amendments of 1976 or by a foreign regulatory authority should be withdrawn or suspended as a result of safety concerns. *See* (Dkt. 40) at 6. Defendant's objection is primarily based on Defendant's assertion that the "regulatory status" of the IVC Filter is irrelevant to Plaintiff's failure to warn claim. *See* (Dkt. 37) at 14-15. Defendant further objects asserting Plaintiff's request amounts to a "fishing

expedition" and that such information is privileged. *See id.* In Plaintiff's Reply, Dkt. 40 at 6, Plaintiff agreed to limit this request to Defendant's sales of Greenfield IVC Filters to Brooks Memorial Hospital in 1999.

Plaintiff argues that such regulatory history is relevant as it may provide evidence of risks which the Filters pose to prospective patients or users. (Dkt. 40) at 6. Courts have held such information is relevant to a failure to warn claim. *See Dyer v. Danek Medical, Inc.*, 115 F.Supp.2d 732, 741 (N.D.Tex. 2000) (holding the regulatory status of a surgically implanted medical device, information unknown to the physician at the time of surgery, was relevant to the plaintiff's failure to warn claim). *See also, supra,* at 17. Defendant has also failed to cite any authority in support of Defendant's assertion that the requested information is subject to any privilege or other protection. Accordingly, Defendant's objections to Plaintiff's Request No. 11 are without merit and Plaintiff's motion with respect to this request is GRANTED.

Request for Production No. 15.

In this request, Plaintiff seeks production of Defendant's organizational charts from 1995 to the present. *See* (Dkt. 37) at 15. Defendant objects asserting lack of clarity, relevancy and overbreadth. Dkt. 37 at 15. In Plaintiff's Reply, Plaintiff agreed to limit this request to the period 1997 to 2001. *See* (Dkt. 40) at 6. According to Plaintiff, such information is relevant to Plaintiff's ability to identify Defendant's employees with knowledge of documented risks associated with the Greenfield IVC Filter. *See* (Dkt. 40) at 6. However, the court finds such request to be redundant to Defendant's response to Interrogatory No. 7 which requests Defendant to identify such persons. *See, supra,* at 12-14. Accordingly, Plaintiff's Motion should be DENIED with respect to this request

without prejudice to renewal in the event Defendant fails to comply with Interrogatory No. 7 as modified by the court.

Defendant's Motion for a Protective Order.

As to Defendant's motion for a protective order pursuant to Fed.R.Civ.P. 26(c), Defendant states that Defendant's request for a protective order is based on Plaintiff's failure to provide more specific product identification. *See* (Dkt. 37) at 16. Specifically, Defendant requests that the court should enter a protective order precluding Plaintiff's Discovery Requests for information concerning other than the specific Greenfield IVC Filter actually implanted in Decedent until such time as Plaintiff has provided specific identification of Defendant's product implanted in Decedent. *Id.* In light of Plaintiff's Notice of Newly Discovered Evidence (Dkt. 41) specifically identifying the type of Defendant's IVC Filter implanted in Decedent as a Stainless Steel Greenfield IVC Filter and Defendant's Response to Plaintiff's Request to Strike (Dkt. 46), Defendant's motion for a protective order is moot and, as such, should be DISMISSED.

CONCLUSION

Based on the foregoing, Plaintiff's Motion (Dkt. 30) is GRANTED in part, and DENIED in part; Defendant's Motion for Protective Order (Dkt. 37) is DISMISSED as moot; Plaintiff's Motion to Strike (Dkt. 41) is DISMISSED as moot. Defendant's responses in accordance with this Decision and Order shall be served within 20 days.

As required by Fed.R.Civ.P. 37(a)(5)(A), Defendant shall show cause not later than 20 days after filing of this Decision and Order why Plaintiff's expenses, including reasonable attorneys fees, incurred in connection with Plaintiff's Motion should not be

awarded to Plaintiff; Plaintiff's response shall be filed not later than 10 days thereafter; any reply by Defendant shall be filed within 5 days. As required by Fed.R.Civ.P. 37(a)(5)(B), Plaintiff shall show cause not later than 20 days after filing of this Decision and Order why Defendant's expenses, including reasonable attorneys fees, should not be awarded to Defendant incurred in connection with Defendant's successful opposition to Plaintiff's Interrogatory No. 7 and Requests for Production Nos. 5, 6 and 15; Defendant's response shall be filed not later than 10 days thereafter, any reply by Plaintiff shall be filed within 5 days. Oral argument shall be at the court's discretion.

SO ORDERED.

/s/ *Leslie G. Foschio*

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LESLIE G. FOSCHIO
UNITED STATES MAGISTRATE JUDGE

Dates: November 22, 2024
Buffalo, New York